K083176

DORMIO TECH
INNOVATIVE SLEEP TECHNOLOGY
A Division of Chad Therapeutics, Inc.

10200 MASON AVE, SUITE 114
CHATSWORTH, CA 91311
PHONE: 800-871-8484
FAX: 818.882.1809

510(k) SUMMARY

JUL 2 8 2008

DORMIO TECH
A division of Chad Therapeutics, Inc.

FloCHANNEL Model FC-100

Date Prepared:	April 22, 2008
Submitter Information:	Dormio Tech A division of Chad Therapeutics, Inc. 10200 Mason Ave, Suite 114 Chatsworth, CA 91311
Official Contact:	Kevin McCulloh Sr. Vice President of R&D, Engineering & RA
Phone:	(800) 871-8484
FAX:	(818) 882-1809
E-mail:	kmcculloh@dormiotech.com
Device Name:	FloCHANNEL Model FC-100
Common Name:	Breathing Frequency Monitor
Classification Name:	Ventilatory Effort Recorder
Classification Reference:	Class II, 21 CFR 868.2375
Product Code:	MNR

Predicate Device Equivalence:

Substantial equivalence is claimed to the Pro-Tech Services, Inc. Pressure Transducer Airflow Sensor, 510(k) # K982293.

Device Description:

The FloCHANNEL, FC-100, Sleep Diagnostic Device accomplishes its intended purpose by providing a method for flow prescription based airway diagnostics as well as a method to measure nasal airflow resistance effects. The device simultaneously measures relative airflow of isolated left, right, and oral passages. The FloCHANNEL, FC-100, provides analog voltage outputs for methods of scoring sleep disordered breathing. The outputs provided are hardware amplified analog voltages from three airflow sensors, hardware amplified nasal summed output, and two microprocessor driven outputs that produce analog voltages to aid in scoring the respiration of a patient.

The FloCHANNEL, FC-100, is dependent on the patient interface unit to be able to compute and detect the respiration patterns of the patient. This accessory is three air filters attached to a nasal and oral cannula. The cannula is of one-piece construction that allows independent pneumatic fluid connection between the FloCHANNEL, FC-100, and the patient's left nasal airway, right nasal airway, and oral airway. The filter shall prevent the transfer of particulates greater than or equal to 0.1 microns in size between the patient and the FloCHANNEL, FC-100. There is one filter per channel on the patient interface unit with independently sealed chambers to prevent cross flow between pneumatic channels.

The FloCHANNEL has an output selection switch that is accessible from the outside of the enclosure and is a four-position two-selector right-angled DIP switch. The purpose of the switch is to allow greater flexibility in the output options to be able to configure to a variety of sleep lab diagnostic signal conditioners. With this switch there is the ability to create four different output voltage ranges.

There are six (6) output connectors on the FloCHANNEL, FC-100. All output connectors are RCA jacks. There is one connector for each output. The outputs are Left Nasal Processed Airflow, Right Nasal Processed Airflow, Oral Airway Processed Airflow, Sum of Left Nasal Processed Airflow and Right Nasal Processed Airflow, Relative Tidal Volume, and IE Marker.

Intended Use:

The FloCHANNEL is intended for use during sleep disorder studies to detect respiratory airflow onto a physiological recorder. A filtered disposable nasal/oral cannula attaches to the patient and connects into the input of the FloCHANNEL device. The outputs of the device provide low-voltage signals that are intended to be input into a physiological recorder.

Contraindications:

The FloCHANNEL device can be used for pediatric patients, two years and older and adult patients including geriatric patients. The device is not intended for pediatrics and infants below two years of age for the purpose of respiration or SIDS monitoring.

Comparison of Technological Characteristics:

Both the Dormio Tech FloCHANNEL and the predicate device are prescription devices, have similar indications for use, similar contradictions, patient populations, patient connections, operating environments, operating temperatures, similar outlet signal voltages and connect to the same physiological recorders for use in sleep disorder studies.

The device has many similar technological characteristics as the predicate device, except that the FloCHANNEL has a relative left naris, right naris and an oral flow input and output signal, whereas the predicate device has only one naris input and output. The FloCHANNEL device also incorporates a state of the art airflow sensor for output signals that that exceed the resolution of the predicate device. The FloCHANNEL device also has two additional low-voltage output signal settings for connection to the widest range of physiological recorders.

Summary of Testing:

All risk assessment, design verification and validation activities were conducted in accordance with the device product requirements to demonstrate that the Dormio Tech FloCHANNEL would perform as intended.

- ✓ The FloCHANNEL passed all of the test criteria established in the FloCHANNEL design verification and validation tests.
- ✓ The FloCHANNEL was proven clinically equivalent or superior to the predicate device.
- ✓ The differences in the new device and the predicate device do not raise new issues regarding safety or effectiveness. Both devices utilize a filtered patient cannula and are low-powered devices that do not have any direct electrical connections or conductive electrical connections to the patient.

Substantial Equivalence:

The device has a similar indications statement as the predicate device.
The differences in the device and the predicate device do not alter the effect or raise new issues of safety or effectiveness.

The FloCHANNEL passed all of the tests and acceptance criteria as outlined in the test procedures. Test data demonstrates equivalence to the predicate device.

Based on the above, we have concluded that the Dormio Tech FloCHANNEL is substantially equivalent to the legally marketed predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2008

Mr. Kevin McCulloh
Senior Vice President of R&D, Engineering & RA
Chad Therapeutics, Incorporated
Dormio Tech
21622 Plummer Street
Chatsworth, California 91311

Re: K081176
Trade/Device Name: FloCHANNEL
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: July 22, 2008
Received: July 23, 2008

Dear Mr. McCulloh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: FloCHANNEL

Indications For Use:

The FloCHANNEL is intended for use during sleep disorder studies to detect respiratory airflow onto a physiological recorder. A filtered disposable nasal/oral cannula attaches to the patient and connects into the input of the FloCHANNEL device. The outputs of the device provide low-voltage signals that are intended to be input into a physiological recorder.

The FloCHANNEL device can be used for pediatric patients, two years and older and adult patients including geriatric patients. The device is not intended for pediatrics and infants below two years of age for the purpose of respiration or SIDS monitoring.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081176